

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

ARBUTUS BIOPHARMA CORPORATION
and GENEVANT SCIENCES GMBH

Plaintiffs,

v.

MODERNA, INC. and MODERNATX,
INC.,

Defendants.

Redacted - Public Version

C.A. No. 22-252-JDW

MODERNA, INC. and MODERNATX,
INC.,

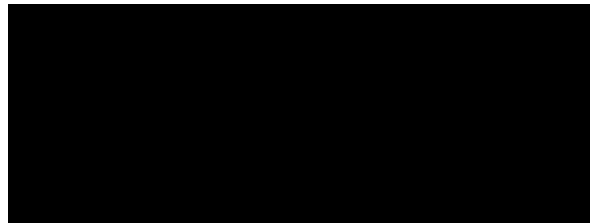
Counterclaim-Plaintiffs,

v.

ARBUTUS BIOPHARMA CORPORATION
and GENEVANT SCIENCES GMBH,

Counterclaim- Defendants.

JURY TRIAL DEMANDED



**PLAINTIFFS' REPLY IN SUPPORT OF MOTION TO EXCLUDE CERTAIN EXPERT
TESTIMONY OF RUTHERFORD, VELLTURO, AND PRUD'HOMME, AND
OPPOSITION TO MOTION TO EXCLUDE CERTAIN TESTIMONY OF MITCHELL**

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TABLE OF ABBREVIATIONS

<u>Abbreviation</u>	<u>Full Description</u>
R.	Moderna's September 5, 2025 Reply in Support of Summary Judgment (D.I. 597)
CM	Plaintiffs' August 22, 2025 Responsive Brief in Opposition to Moderna's Summary Judgment and In Support of Plaintiff's Cross-Motion for Summary Judgment (D.I. 564)
OB	Plaintiffs' July 25, 2025 Opening Brief In Support of Motion for Summary Judgment (D.I. 519)
M.OB	Moderna's July 25, 2025 Opening Brief in Support of Motion for Summary Judgment (D.I. 508)
Pl. R.	Plaintiffs' September 5, 2025 Reply Brief In Support of Motion for Summary Judgment (D.I. 591)
PSOF	Plaintiffs' September 19, 2025 Affirmative Statement of Uncontested Facts, including Moderna's Responses and Plaintiffs' Reply
MSOF	Moderna's September 5, 2025 Statement of Uncontested Facts, including Plaintiffs' Responses and Moderna's Reply (D.I. 599)
M.Ex.	Exhibit to the July 25, 2025 Declaration (M.Exs. 1-81), and September 5, 2025 Declaration (M.Exs. 82-119) of Mark McLennan
M2.Ex.	Exhibit to the August 22, 2025 Declaration of Mark McLennan
Ex	Exhibits to the July 25, 2025 Declaration (Exs 1-29), August 22, 2025 Declaration (Exs 30-99), September 5, Declaration 2025 (Exs 100-121), and September 19, 2025 Declaration Exs 121-140) of Matthew W. Lachman
M.MTE	Moderna's July 25, 2025 Opening Brief in Support of Motion to Exclude Brill and Pitts (D.I. 511)
MTE	Plaintiffs' August 22, 2025 Response to Moderna's Motion to Exclude and Opening Brief in Support of Motion to Exclude (D.I. 561)
M.MTE R.	Moderna's September 5, 2025 Reply in Support of Motion to Exclude (D.I. 596).
SR	Plaintiffs' September 19, 2025 Sur-Reply in Support of Plaintiffs' Cross-Motion for Summary Judgment

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¹ Unless noted, all emphasis is added, and internal citations and quotations are omitted.

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I. Moderna's Reply Brief Is Procedurally Improper.

In a brief twice as long as permitted by the Court's Order (D.I. 545), Moderna accuses Plaintiffs of failing to disclose its fraudulent inducement argument properly, and of not preserving some of the motions to exclude filed in connection with summary judgment. These false accusations are a transparent attempt to justify the impropriety of Moderna's own brief and to distract from the merits of Plaintiffs' motions to exclude. The very interrogatory response that Moderna cites, but apparently did not bother to read, resolves the fraud issue—it contains Plaintiffs' disclosure that “Moderna's inducement to the Government to enter into the -0100 Contract, based on misrepresentations, voids any applicability of FAR Clause 52.227-1.” M.Ex. 119 (Plaintiffs' Rog 14 Resp.) at 5. Despite quibbling with numerous other interrogatory responses, Moderna did not ask for additional details or suggest this response was insufficient.

The claim that Plaintiffs failed to preserve their motions to exclude is similarly lacking and is disproven by both the relevant Order and the chronology of events before Judge Goldberg. Unlike this Court's policies, Judge Goldberg's do not call for motions to exclude in connection with summary judgment. Ex 129 (J. Goldberg Policies). It was only on June 25, 2025—almost two months after the parties disclosed their *Daubert* motions—that Judge Goldberg issued an Order providing for additional motions to exclude at summary judgment. D.I. 485 ¶ 6. That Order did not restrict the subject of those motions. Indeed, it maintained separate *Daubert* briefing, as addressed in the parties' letters, setting it for November 2025. *Id.* ¶ 7. There was thus no requirement that the motions to exclude ordered in June be disclosed in a letter two months earlier.

Ultimately, Moderna has no justification for its overlength brief. The Court's August 19, 2025 Order, D.I. 545, provided just 10 pages for Moderna's September 5, 2025 MTE Reply, yet Moderna's brief was 20 pages. In a footnoted excuse—the need for which shows Moderna knew it was not complying with the Court's Order—Moderna tries to justify the increased pages by

citing to the page limit for the *summary judgment reply* (despite separately filing a 20-page summary judgment reply). M.MTE R. 1 n.3. There was no good-faith basis to ignore page limits.

Nor was Moderna entitled to additional pages for its new motion regarding Dr. Mitchell. First, even without that motion, Moderna exceeds the 10-page limit by 60%. Second, the new motion is itself procedurally improper. Judge Goldberg’s Order provided for a “*contemporaneous* motion” to be filed with motions for summary judgment. D.I. 485 ¶ 6. The Order does not provide for new motions filed in reply, based on evidence identified in opposition. The briefing schedule (D.I. 545) clearly does not provide for any briefing relating to summary judgment after the September 19 deadline. And if Moderna truly thought changed circumstances justified an additional motion (there were none, as Plaintiffs disclosed their misrepresentation theory in discovery), it should have conferred with Plaintiffs or sought leave from the Court. It did neither.

As a result, and consistent with the Court’s Order (D.I. 545), Plaintiffs have set forth in ten pages their reply in support of the motions to exclude filed on August 22, 2025. Although the Court should not reach the untimely motion concerning Dr. Mitchell, Plaintiffs also respond substantively to that motion (but have kept the overall length to the 20 pages Moderna used).

II. The Same Legal Rules That Apply To Plaintiffs’ Experts Also Apply To Moderna’s.

Moderna disclosed Rutherford and Vellturo to opine that a series of outcomes connected to COVID-19 vaccination were “benefits to the Government.” M.Ex. 30-A ¶ 26; M.Ex. 31-A ¶ 6. Now, at summary judgment, Moderna has reversed course. It proposes to ignore entirely the question of whether the infringing doses were “for the Government,” instead asking only whether the Government consented. R. 2. Having discarded its prior theory, Moderna tries to lay the blame at Plaintiffs’ feet. Moderna thus argues it was Plaintiffs who urged a “fact-heavy” analysis, R. 3, even though it was Moderna who first served expert reports on benefits to the Government. Those reports engaged in factually-intensive analysis, including assessing and projecting outcomes on

issues ranging from the number of hospitalizations averted, to lives saved, to changes in tax revenue. M.Ex. 30-A ¶¶ 74, 86; M.Ex. 31-A ¶¶ 42, 50-52. Plaintiffs—who do not bear the burden of proof on § 1498—merely responded to that evidence, offering expert testimony in rebuttal.

Moderna makes no real attempt to distinguish the types of opinions offered by Rutherford and Vellturo from those of Brill and Pitts. Indeed, Moderna claims Pitts and Brill “do not directly contradict or rebut” its own experts, based on only Pitts and Brill’s agreement with some underlying factual evidence. M.MTE R. 3. But Moderna’s experts did not just offer rote factual recitations—the central thrust of their reports is the opinion that those facts equate to ***Government*** benefits. M.Ex. 30-A ¶ 26; M.Ex. 31-A ¶ 6. Brill and Pitts directly rebut that opinion.

Moderna contends this rebuttal is not permitted, arguing it is “inappropriate for experts” to testify about what constitutes a “benefit for the Government” because it is “a legal question of statutory interpretation.” M.MTE 6. Moderna also argues that opinions about “***what constitutes a benefit to the Government***” are “unhelpful to the trier of fact because what constitutes a benefit is not a factual question for the jury to resolve.” *Id.* at 7. Plaintiffs disagree that this warrants exclusion—expert witnesses do not violate the prohibition on offering legal opinions when they “interpret and analyze factual evidence and apply that factual evidence to a legal framework to render an opinion.” *In re Intel Corp. Microprocessor Antitrust Litig.*, 526 F. Supp. 2d 461, 466 (D. Del. 2007). And on summary judgment, the line between permissible analysis and impermissible legal opinions is less important, because there is no risk of the opinions “confus[ing] a jury.” *Id.* However, as Moderna has retreated, and neither party now advocates a fact-intensive evaluation, the Court need not address the propriety of this expert evidence. But if the Court were to agree with Moderna about the proper scope of expert testimony, it should apply that rule evenly.

Moderna offers no basis to apply the rules unequally. It simply avers that equal treatment—and the “waterfowl analogies” that illustrate it—are “inapposite” in this context. M.MTE R. 5. A whole flock of courts disagree. The law of expert admissibility is clear: “sauce for the goose is sauce for the gander; if it is improper for [Plaintiffs’] experts to expound on [a topic], the same would be true of [Moderna’s] experts.” *Lipocine Inc. v. Clarus Ther., Inc.*, 2020 WL 4794576, at *10 (D. Del. Aug. 18, 2020); *United States v. Knowles*, 889 F.3d 1251, 1257-58 (11th Cir. 2018) (“[I]n the law, what’s sauce for the goose is normally sauce for the gander. We have applied this common-sense principle of equal treatment in the context of expert witnesses.”); *Eck v. Yellow Transp.*, 2007 WL 4440959, at *1 (E.D. Pa. Oct. 16, 2007) (Plaintiff enlisted “two medical experts ... [w]hat is good for the goose is good for the gander—two experts each on the subject.”).

Both parties’ experts opine about what constitutes a benefit to the Government; should such testimony be verboten, “if mine, then also yours,” M.MTE R. 7, is exactly the right outcome. *See Lipocine*, 2020 WL 4794576, at *10.

III. Vellturo’s Failure to Follow the Procedure Set Out In His Report Merits Exclusion.

Vellturo’s description of the costs considered in his analysis illustrates the fundamental flaw in his conclusion. As Moderna notes, Vellturo explained that the “relatively short term costs I discussed in my Opening Report can reasonably be given *more weight* in an economic benefit analysis” whereas “longer term impacts should be *discounted more heavily* in any event once one has accounted for uncertainty and time value of money.” M.MTE R. 9 (citing M.Ex.31-B ¶ 31).

Vellturo opined only that these costs should be given less weight, not excluded. Had he adjusted his analysis accordingly—including the costs but discounting them—Plaintiffs’ criticisms might go to weight, as in the case Moderna cites, where the issue was *how* the expert adjusted for the statistical errors the other party raised. *Karlo v. Pittsburgh Glass Works*, 849 F.3d 61, 82-83 (3d Cir. 2017). But despite acknowledging that longer-term costs, appropriately discounted,

should be included in his benefit analysis, Velturo omitted them entirely. M.Ex. 62 (Brill) ¶¶ 45, 49. Thus, as in *Microstrategy Inc. v. Bus. Objects*, Velturo’s analysis “overlook[ed] factors that render [his] testimony unreliable and/or speculative.” 429 F.3d 1344, 1355-56 (Fed. Cir. 2005).

IV. The Court Should Exclude Prud’homme’s Legally Inapt Indefiniteness Opinions.

Dr. Prud’homme’s indefiniteness opinions included legally irrelevant arguments about the POSA’s ability to assess infringement. MTE 14-20. Moderna attempts to justify these opinions by misreading Federal Circuit precedent, mischaracterizing its own expert’s testimony, and citing unrelated (but also legally flawed) opinions. None of these arguments move the needle, and the Court should exclude Dr. Prud’homme’s opinions.

A. Federal Circuit precedent precludes Moderna’s arguments.

The Federal Circuit’s *SmithKline* decision squarely forecloses Dr. Prud’homme’s opinions. MTE 14-20. Moderna attempts to cabin *SmithKline* to circumstances where the defendant solely could not assess infringement of its own accused product. *See* M.MTE R. 11-12 (Moderna arguing that “[b]ecause the accused product had trace amounts of PHC hemihydrate, the district court held the claims to be indefinite”), 12 (arguing that *SmithKline* involved “a defendant who cannot accurately measure a defined compound”). Moderna applies this phantom distinction to argue that Dr. Prud’homme’s opinions related to measurement “generally” rather than to Moderna’s infringement specifically, urging that only the latter is impermissible. *Id.* at 13.

Moderna’s distinction is not borne out by *SmithKline* or subsequent cases. The district court’s concern in *SmithKline* (which the Federal Circuit rejected) was that the claim would cover “a single undetectable crystal” generally—it did not relate specifically to the accused product as Moderna contends. 403 F.3d 1331, 1335 (Fed. Cir. 2005) (“The district court reasoned that SmithKline’s interpretation would place *potential infringers* in the untenable position of never knowing whether their product infringes because even a single undetectable crystal of PHC

hemihydrate would infringe.”). The Federal Circuit held that this general concern—it was “undetectable” for everyone, not only Apotex—was irrelevant to indefiniteness: “[T]he trial court feared that potential infringers would not be able to determine (and avoid) infringement if they cannot detect the claimed compound. This reasoning misses the proper purpose of the definiteness requirement.” *Id.* at 1340. The *SmithKline* holding clearly was not confined to non-infringement arguments about the accused product specifically, as it addressed “potential infringers” writ large.

Moderna acknowledges that the proper inquiry is “whether the scope of the claim is clear.” M.MTE R. 12. In *SmithKline*, despite encompassing “a single undetectable crystal,” the “scope of [the] claim [was] clear.” 403 F.3d at 1335, 1341. Likewise here, the scope of the claims is unambiguous and undisputed. SR 6, 9-10. Moderna is free to argue that a single infringing particle (or fully encapsulated mRNA) is “undetectable” as a purported defense to infringement, but *SmithKline* could not be clearer that this is not a valid indefiniteness argument.

Moderna half-heartedly criticizes Plaintiffs’ reliance on *SmithKline* because it was decided before the Supreme Court’s *Nautilus* case, M.MTE R. 11, despite previously citing that case itself, M.OB 33. But *none* of Moderna’s cases suggests that *Nautilus* or any other case overruled *SmithKline*. The Federal Circuit recently reaffirmed the key holding of *SmithKline* in rejecting an indefiniteness argument that only raised a “question of infringement.” *Ironburg Inventions Ltd. v. Valve Corp.*, 64 F.4th 1274, 1290 (Fed. Cir. 2023) (“The test for indefiniteness does not depend on a potential infringer’s ability to ascertain the nature of its own accused product to determine infringement, but instead on whether the claim delineates to a [POSA] the bounds of the invention.” (quoting *SmithKline*, 403 F.3d at 1340-41)). Moderna does not suggest that *Ironburg* (or any other case) questioned the holding of *SmithKline*.

Moderna cites no case invalidating a claim as indefinite because infringement was difficult

to assess. Rather, its cited cases (at 12) involved situations where claim *scope* was uncertain. In *Pacific Coast*, the claim recited a “newly coined characteristic” called “scored flexural strength,” but the specification did not disclose “what the value represents” or how to “measure this new characteristic,” 816 F. App’x 454, 459 (Fed. Cir. 2020), rendering the claims’ scope uncertain. Likewise, in *Forest Laboratories*, the claims required a “human PK study,” but did not identify the “‘human PK study’ on which to rely,” which rendered the claims ambiguous because “human PK studies vary widely.” 2016 WL 54910, at *9 (D. Del. Jan. 5, 2016). *GE Lighting Solutions* denied a motion to strike because the expert *had* adequately testified that there was ambiguity about the “scope or boundaries of” two claim terms. 2015 WL 1564945, at *2 (N.D. Ohio Apr. 8, 2015). Here, by contrast, the testimony Plaintiffs move to exclude does *not* relate to any ambiguity in what the claims mean or cover. Finally, Moderna cites (at 14) language from the background legal discussion of *Niazi*, but the quote is about the claims “*providing clarity* such that a [POSA] could determine whether or not an accused product or method infringes,” 30 F.4th 1339, 1346-47 (Fed. Cir. 2022). That accords with the case’s holding that the claims were definite because they “provide[d] objective boundaries for” the POSA. *Id.* at 1349-50. Here too, there is no dispute that the claims provide clear, objective boundaries about what they cover. SR 6, 9-10.

B. Dr. Prud’homme’s Lipid Composition Patent opinions are improper.

As explained, several of Dr. Prud’homme’s opinions concerning the Lipid Composition Patents turned not on the scope of the claims (which Moderna now concedes encompass single particles), but rather on the supposed difficulty of detecting those claimed particles. MTE 14-16.

Moderna argues that Dr. Prud’homme’s opinions were not about “measuring or assessing infringement.” M.MTE R. 13. Moderna’s position is baffling. Dr. Prud’homme opined that it is “impossible to measure” the claimed “molar ratios” of “individual LNPs.” M.Ex. 83 (Prud’homme) ¶ 229; *id.* ¶ 230 (“I am not aware of any methods that have been validated and/or

generally accepted within the scientific community to be able to measure the composition of a single LNP.”). Those opinions are about the POSA’s ability to detect infringement, regardless of whether Moderna’s expert used that specific word. Indeed, they bear a striking resemblance to the district court’s erroneous concern in *SmithKline* about the claims covering a “single undetectable crystal,” which the Federal Circuit held did not go to indefiniteness. 403 F.3d at 1335, 1340-41.

Dr. Prud’homme’s opinions about “in-process” particles are no less improper. He explicitly bases his indefiniteness opinions on Plaintiffs’ infringement arguments and Moderna’s manufacturing process (as set forth in its BLA, the regulatory submission for the COVID-19 vaccine). M.Ex. 84 (Prud’homme Reply) ¶ 158 (discussing the “composition Plaintiffs have accused of infringement” and “Moderna’s BLA”; contending that Plaintiffs’ alleged infringement “argument likewise makes the claims indefinite”). Moderna’s Statement of Facts admits that the details of Moderna’s manufacturing process are “significant to Dr. Prud’homme’s indefiniteness opinions,” citing his non-infringement report. PSOF ¶ 30.

Moderna justifies Dr. Prud’homme’s opinions by arguing that they relate to “the inability to take a measurement *generally*,” rather than “measuring *infringement* by Moderna’s COVID-19 vaccine.” M.MTE R. 13. That assertion is simply false with respect to Moderna’s arguments about “in-process” particles in its manufacturing process. And in any case, Moderna’s distinction finds no support in *SmithKline* or any other case Moderna cites, as explained above. *Supra* IV.A.

Moderna also contends that Dr. Prud’homme’s opinions go to the “metes and bounds of the invention.” M.MTE R. 14. Moderna provides no explanation or support for this assertion. Neither Dr. Prud’homme nor Moderna identify any ambiguity about what the claims mean or cover. SR 6; PSOF ¶¶ 16-18.

Moderna argues that Dr. Prud’homme opined that different fractionation techniques may

yield “different results.” M.MTE R. 14. Moderna fails to explain why this argument—which Plaintiffs addressed separately, CM 28-29; SR 6-8—is relevant to its expert’s violation of *SmithKline*. In any event, Moderna is wrong on both the facts and law. Factually, despite contending that different fractionation results “actually were” achieved, M.MTE R. 14, Moderna’s citations do not identify inconsistent fractionation data (much less the legally required outcome-determinative differences), and the data Moderna cites elsewhere are similarly inapt. *See* SR 7-8; PSOF ¶ 92. Legally, as Judge Bryson recently explained, the “problem of inconsistency in test results is entirely different from the problem of indefiniteness” in Moderna’s *Teva and Dow* cases. *Kaneka Corp. v. Designs for Health, Inc.*, 2025 WL 1684677, at *5 (D. Del. June 16, 2025). The measurement differences Dr. Prud’homme speculates may exist do not render the meaning of the claim terms themselves unclear and thus are irrelevant to indefiniteness. *Id.*; SR 6-8.

C. Dr. Prud’homme’s improper ’651 Patent opinions should be excluded.

Moderna’s arguments concerning the ’651 patent (at 14-15) are similar to its arguments about the Lipid Composition Patents and fail for the same reasons. As explained, Dr. Prud’homme opined that the ’651 patent claims were indefinite due to the supposed “difficulty of measuring infringement.” MTE 18. Although Moderna disputes the basis for its argument, M.MTE R. 14, it quotes Dr. Prud’homme’s opinion that there is “no reliable way to quantify any nucleic acid that” is partially encapsulated, *id.* at 14-15. Putting aside the irrelevance of quantifying partially encapsulated mRNA, CM 34, Moderna’s quote (14-15) is plainly about *measuring* encapsulation for purposes of assessing infringement. That Dr. Prud’homme avoided the word “infringement” does not change the substance of his opinions. Many of Dr. Prud’homme’s other opinions similarly address the difficulty of measuring fully or partially encapsulated mRNA. MTE 18-20. Those arguments are irrelevant to indefiniteness under *SmithKline* and its progeny. *Supra* IV.A.

Moderna suggests that its expert *also* opined that the term “fully encapsulated” is unclear.

M.MTE R. 15. But Moderna continues to rely on the same conclusory deposition excerpt, *see* M.OB 30 (quoting same M.Ex. 56 at 180:21–182:21); CM 31, and the failure of Moderna and Dr. Prud’homme to identify any concrete ambiguity about the meaning of “fully encapsulated,” in view of the Court’s construction, mandates summary judgment for Plaintiffs. SR 9-10. In any event, Dr. Prud’homme’s (conclusory) opinions about purported claim scope ambiguity cannot save his otherwise improper measurement-related opinions, which should be excluded.

Finally, Moderna relies on Blenke to argue that different encapsulation measurements may yield different results. M.MTE R. 15 (citing M.Ex 61[] ¶ 136). Moderna’s argument is perplexing, as Plaintiffs did not move to exclude the paragraph of Dr. Prud’homme (¶ 136) that Moderna cites (*see* MTE 19-20), and Plaintiffs addressed this issue separately, CM 32-33. Regardless, Moderna’s arguments are meritless, including because there is no evidence that Blenke’s methods were used to measure encapsulation at the priority date and because Blenke did not use mRNA. *Id.* Further, Moderna cannot show that any hypothetical differences in encapsulation measurements create ambiguity in the scope of the claims, rendering them legally irrelevant. *Supra* IV.B. Given the Court’s *Markman* decision, there is no such ambiguity. SR 9-10.

For the foregoing reasons, the cited paragraphs of Dr. Prud’homme’s reports (MTE 17, 19-20) improperly go to non-infringement, not indefiniteness, and should be excluded.

V. The Court Should Deny Moderna’s Motion To Exclude Dr. Mitchell’s Opinions.

Moderna seeks, in a procedurally improper motion, *supra* I, to exclude opinions of Dr. Mitchell, Plaintiffs’ infringement expert, on spurious grounds. M.MTE R. 16-20. Moderna principally focuses on its baseless claim that Dr. Mitchell’s opening report is not his own work, M.MTE R. 16, which gravely misstates the facts and finds no support in precedent. Dr. Mitchell’s report was prepared in the same way as Moderna’s own experts’ reports, in collaboration with counsel. The real reason for Moderna’s motion is not any error in Dr. Mitchell’s report—the

substance of which Moderna ignores—but that Dr. Mitchell’s report decisively establishes infringement, to which Moderna has no response. That Moderna advanced no responsive testing to dispute infringement does not support sweeping Plaintiffs’ infringement evidence under the rug.

A. Plaintiffs disclosed that Moderna’s fraud precluded its § 1498 defense.

Moderna briefly raises three procedural arguments (M.MTE R. 16) asserting that Plaintiffs did not adequately disclose a fraudulent inducement theory. None have merit.

First, Moderna asserts that Plaintiffs failed to disclose during discovery that Moderna’s misrepresentation to the Government as to its patent infringement precluded its § 1498 defense, *id.*, but inexplicably ignores that Plaintiffs unambiguously did just that. Plaintiffs’ interrogatory response regarding its argument that Moderna’s sales “are not subject to [§ 1498]” (M.Ex. 119 at 2) disclosed that “Moderna’s inducement to the Government to enter into the -0100 Contract, based on misrepresentations, voids any applicability of FAR Clause 52.227-1.” M.Ex. 119 at 5 (citing *SmartSignal Corp. v. Expert Microsystems, Inc.*, 2006 WL 1343645 (N.D. Ill. 2006)). And that response specifically referenced Moderna’s “misrepresentations to the Government *about the scope of Moderna’s infringement of Plaintiffs’ patents.*” *Id.* The parties exchanged countless letters about the sufficiency of discovery responses, but not once did Moderna seek more details as to this response or otherwise suggest it was insufficient. Thus, Moderna’s charged rhetoric deriding Plaintiffs’ argument as “frivolous,” “untimely,” and “never disclosed during discovery,” MSOF ¶ 146, M.MTE R. 16, rests on a flagrant mischaracterization of Plaintiffs’ discovery response, MSOF ¶ 146 (citing M.Ex. 119 at 2-17).

Second, Moderna observes that Plaintiffs’ fraud argument “was not pled,” M.MTE R. 16, but Moderna invoked § 1498 only as an affirmative defense. D.I. 321 at 85. Thus its reference to the pleading in *SmartSignal, Inc.*, R. 7, in which the defendant asserted § 1498 as a *counterclaim* (necessitating a pleaded response), D.I. 44, No. 1:02-cv-07682), is inapposite. Plaintiffs were “not

required or permitted to file any responsive pleading at all” in response to Moderna’s § 1498 affirmative defense. *Soler v. Fernandez*, 2015 WL 5771929, at *3 (M.D. Pa. Sept. 29, 2015).

Third, Moderna asserts that its misrepresentation to the Government concerned the ’069 patent, which “is no longer asserted in the case” and thus “lacks relevance.” M.MTE R. 16. Not so. All Lipid Composition Patents—the ’069 patent and the patents asserted at trial—share the same specification, and Moderna itself argues that the asserted claims recite “broader lipid ranges” than the ’069 patent. D.I. 556 at 6. Moderna’s awareness that it infringes the ’069 patent (CM 14-16) necessarily means that it was aware it infringes the broader asserted claims—including the ’435 patent claims Moderna tried but (like the ’069) failed to invalidate at the PTAB. OB 1. Moderna falsely informed the Government that it did not infringe the ’069. Ex 48 (Mitchell ¶¶ 680, 738) (’069 infringes under DOE). And even were Moderna’s representation as to the ’069 patent accurate (it is not), it still committed fraud by not disclosing that it infringed other asserted patents. *See* 26 Williston on Contracts § 69:2 (4th ed.) (“affirmative misrepresentation is not required.”).

B. Dr. Mitchell provided substantial input into his report.

Moderna devotes the bulk of its motion to exclude Dr. Mitchell’s opinions to its far-fetched claim that his opening report opinions are not his own “but [those] of Plaintiffs’ counsel.” M.MTE R. 16. Although Moderna nominally seeks exclusion of Dr. Mitchell’s opinions related to “§ 1498 and prosecution history estoppel,” *id.*, its arguments do not address Dr. Mitchell’s substantive analysis of those issues, nor *any* of his substantive opinions, but rather the time Dr. Mitchell spent working on his report, M.MTE R. 17-18. To be clear, Moderna will seek to exclude the *entirety* of Dr. Mitchell’s opinions on this same rationale. *See* M.MTE R. 16 n.6. The Court should reject Moderna’s fanciful claim, because Dr. Mitchell gave uncontroverted testimony that he “wrote the opening report in collaboration with counsel,” Ex 132, 13:22-24; he testified (without the benefit of his billing records) to spending “*at least 40 hours or more* preparing this report,” *id.*, 21:2-5;

and Moderna identifies not one criticism of Dr. Mitchell’s expertise or the report’s substance.

No case—*none*—supports Moderna’s approach of imposing an hours threshold for an expert report, much less one based on Moderna’s mischaracterization here. Rather, “exclusion of expert testimony because the expert is ‘nothing more than a “mouthpiece”’ for [counsel] requires commensurately compelling evidence that the expert effectively signed his name onto the report without looking at its contents.” *TQ Delta, LLC v. 2Wire, Inc.*, 2021 WL 2685654, at *3 (D. Del. June 30, 2021). Moderna does not even acknowledge this court’s standard, let alone attempt to meet it; indeed, Moderna exclusively cites out-of-circuit cases in support of its motion to exclude Dr. Mitchell. Because Dr. Mitchell easily clears the governing standard requiring “substantial input into what was put into the report,” Moderna’s motion should be denied. *Id.*

The reason Moderna focuses on hours, pages, and (absurdly) spreadsheet cells, M.MTE R. 17-18, rather than the substance of Dr. Mitchell’s opinions, is plain: Moderna has no answer on the merits. M.MTE R. 16 n.6. Dr. Mitchell is Plaintiffs’ sole expert addressing the central issue for trial, Moderna’s infringement of the asserted patents. In his opening report, Dr. Mitchell analyzed Moderna’s infringement extensively, assessing fractionation data from testing conducted (by Dr. Schuster) on 67 samples of Moderna’s COVID-19 vaccine, Ex 48 ¶¶ 497-99, along with Moderna’s Certificates of Analysis and its own fractionation studies, Ex 48 ¶¶ 464-476, 611-613. Moderna had a full opportunity to rebut that testing with testing evidence of its own. Instead, Moderna—a leading company in the field of mRNA therapeutics, with the undeniable capacity to conduct such testing—submitted *no* testing from *any* sample to rebut Dr. Mitchell’s infringement analysis. *See* Ex 128 (Mitchell Reply) ¶ 433. That Moderna opted for a meritless motion to exclude Dr. Mitchell’s opinions confirms the weakness of its infringement defense.

In any event, Moderna’s arguments about Dr. Mitchell’s drafting process are inaccurate

and irrelevant, and they fail for multiple reasons, as set forth below.

Dr. Mitchell wrote his report. Moderna's assertion that Dr. Mitchell's opening report is "that of Plaintiffs' counsel," not Dr. Mitchell, is utterly devoid of support. M.MTE R. 16. Dr. Mitchell testified consistently that he "**wrote the opening report** in collaboration with counsel," Ex 132, 13:22-24, in accordance with Rule 26 and precedent. Fed. R. Civ. P. 26(a)(2)(B), Advisory Committee Notes; e.g., *TQ Delta*, 2021 WL 2685654, at *2 (the rules "recognize that counsel may participate in the preparation of expert reports" so long as report "reflects the testimony to be given by the witness"); *Advanced Med. Optics, Inc. v. Alcon, Inc.*, 2005 WL 782809, at *9-10 (D. Del. Apr. 7, 2005); *Inventio AG v. Thyssenkrupp Elevator Am. Corp.*, 2014 WL 174301, at *1 (D. Del. Jan. 14, 2014). Moderna cannot controvert this testimony, which easily distinguishes its lead case. In *Numatics*, 66 F. Supp. 3d 934, 941–42 (E.D. Mich. 2014) (M.MTE R. 18-20), the expert testified explicitly that "counsel wrote [his] report," not him, and he reviewed it "for only a couple of hours before signing it." 66 F. Supp. 3d at 941, 943. Further, his report was substantively defective, as it merely "mimic[ked]" the defendant's "invalidity contentions, provide[d] no basis for concluding that prior art references would be combined, ... and reache[d] a conclusion without knowing the relevant factors." *Id.* at 942. Even worse, the expert did not comprehend his report; it addressed obviousness, but the expert "admitted that he had no idea what 'obviousness' means." *Id.* at 944.

The facts here differ drastically from *Numatics*. Dr. Mitchell testified that he "wrote the opening report in collaboration with counsel," which the authority above permits expressly and is also how Moderna's experts prepared their reports. Ex 130 (Anderson) 143:17-144:2 (testifying "we wrote" his report, meaning Anderson "in collaboration with the lawyers"); Ex 133 (Fenton) 39:17-21 ("collaborated with counsel" on report); Ex 134 (Godshalk) 12:15-21 (prepared report "[w]ith help from counsel, of course"); *NetFuel, Inc. v. Cisco Sys. Inc.*, 2020 WL 1274985, at *3

(N.D. Cal. Mar. 17, 2020) (distinguishing *Numatics* where “counsel did not ‘ghost-write’” report). Moderna alleges no “mimic[king]” of Plaintiffs’ filings, *Numatics*, 66 F. Supp. 3d at 942, or *any substantive criticism* of Mitchell’s analysis. This case bears no resemblance to *Numatics*.

Moderna asserts that Dr. Mitchell was “unable to answer” questions at deposition, M.MTE R. 19, but its three citations refute that charge. First, Moderna criticizes Dr. Mitchell for not offering an off-the-cuff definition of the term “liposome,” *id.* (citing M.Ex. 88, 30:10-32:21), but that term is not used in any of the asserted claims, and Dr. Mitchell thus did not address its meaning in his report, M.Ex. 88, 31:8-11. Critiquing an expert’s deposition testimony on “subjects ... ancillary to [the expert’s] primary” opinions cannot support exclusion, and here, the generic meaning of “liposome” is wholly irrelevant. *First Quality Tissue v. Irving Consumer Prods.*, 2022 WL 958089, at *14 (D. Del. Mar. 30, 2022). Indeed, Moderna’s expert Dr. Anderson similarly declined to define generally the term “SPLP” (stable plasmid lipid particle) that he used repeatedly in his reports. Ex 130 (Anderson), 75:17-76:6; *e.g.*, Ex 136 (Anderson) ¶¶ 83, 146, 534, 545.

The same is true of Moderna’s second critique regarding Dr. Mitchell’s testimony about “a trade secret lawsuit,” where Moderna points only to the fact that Dr. Mitchell answered questions by reading “from his report.” M.MTE R. 19. Of course, there is nothing improper about an expert referring to his report to answer questions; Moderna’s experts repeatedly did the same, *e.g.*, Ex 130 (Anderson) 55:25-56:19, 140:15-142:1, 221:1-21; Ex 137 (Prud’homme) 154:15-155:6; Ex 133 (Fenton) 39:7-11. And Dr. Mitchell did not need to provide further gloss on the subject of Moderna’s questioning—what it means to settle a lawsuit “without concession of liability,” an “ancillary” issue at best. Ex 132, 101:16-104:12; *First Quality*, 2022 WL 958089, at *14. Moderna’s third example further illustrates why it was appropriate for Dr. Mitchell to use his report to answer questions. In the cited testimony (M.MTE R. 19), Moderna posed an obtuse question

regarding Dr. Mitchell's billing rate, where a simple "yes" would have been inaccurate, and Dr. Mitchell thus accurately answered by referencing his full billing rate from his report. M.Ex. 88, 17:5-23. That Moderna resorts to nitpicking Dr. Mitchell for not memorizing the details of his billing rate only illustrates that it has no viable critique of Dr. Mitchell's infringement opinions or his ability to answer questions regarding his report, on which Moderna's silence speaks volumes.

In contrast to Dr. Mitchell, Moderna's experts revealed total unfamiliarity with significant, substantive portions of their reports. For example, Dr. Anderson's report repeatedly addressed Moderna's purported research and development regarding its COVID-19 vaccine. Ex 6 (Anderson Reply) ¶¶ 185, 261-64, 277; Ex 140 (Anderson Reply) ¶¶ 284-85. Yet at deposition, Dr. Anderson testified that he did not even "recall" having "reviewed materials related to Moderna's research and development for its COVID vaccine," let alone having offered opinions about them. Ex 130 (Anderson), 36:11-14; *compare id.* at 34:22-35:1 [REDACTED]

[REDACTED], with Ex 140 (Anderson Reply) ¶ 284 [REDACTED]. [REDACTED]. Similarly, Dr. Anderson testified that he "can't remember the thought processes" or otherwise articulate how he arrived at the formulation that his report asserts was obvious from the prior art. Ex 130, 234:8-236:4; Ex 136 (Anderson) ¶ 986. Thus, in marked contrast with Dr. Mitchell, Dr. Anderson was unaware of an entire topic of his reports and the core basis for his obviousness opinions.

None of Dr. Mitchell's cited testimony supports exclusion, and, regardless, his credibility "can be appropriately addressed during cross-examination." *TQ Delta*, 2021 WL 2685654, at *3.

Dr. Mitchell invested substantial time in his report. Moderna baldly mischaracterizes Dr. Mitchell's contributions to his report. Moderna asserts that Dr. Mitchell spent "40 total hours of work" on his report, M.MTE R. 18, but that is wrong: he testified, without consulting billing

records, that he spent “*at least 40 hours or more* preparing this report,” Ex 132, 21:2-5, although he of course had not memorized the “specific number of hours,” *id.* at 20:6-12. In fact, Dr. Mitchell spent 92 hours on his report. 9/19/25 Lachman Decl. ¶ 2; Ex 139. And while Moderna seizes on the two weeks Dr. Mitchell had to review Moderna’s confidential documents, M.MTE R. 17, it ignores that substantial portions of his report do not involve Moderna’s confidential information, including his analysis of analytical techniques and Plaintiffs’ research leading to the asserted patents. *E.g.*, Ex 124 at 2-3 (Sections 1-8). Moderna’s assertion that Dr. Mitchell had to “perform all of the work for his report in a mere 14 days” is thus plainly false. M.MTE R. 18.

Moderna likewise comically inflates the extent of materials Dr. Mitchell reviewed and drafted in that time to claim it was an “impossibility.” M.MTE R. 17. For starters, Moderna makes much of the “more than 2 million cells of data” in the spreadsheets attached as appendices to his report, M.MTE R. 17, but of course, anyone with even passing familiarity with spreadsheets knows that Dr. Mitchell did not sit at a keyboard manually typing numbers into “2 million cells.” Rather, as he explained (but Moderna ignores), his spreadsheets used “fairly straightforward *calculations* that are done based on the molecular weight of the [lipid] components,” which Dr. Mitchell performed to “calculate[] the molar ratio” for relevant lots with respect to infringement. Ex 132, 190:5-13; Ex 48 (Mitchell) ¶¶ 456-58. Moderna requested, and Plaintiffs produced, the formulas Dr. Mitchell used to perform these calculations, which populate the cells at the mere push of a button. Ex 131. Again, Moderna alleges *not one error* in any of those 2 million cells. Nor does Moderna cite a single line of deposition testimony suggesting that Mitchell was unfamiliar with that analysis, about which he testified in detail, *e.g.*, Ex 132, 196:2-197:25, 122:16-138:7.

Similarly, Moderna criticizes Dr. Mitchell’s review of Moderna’s confidential documents and deposition transcripts, irrelevantly computing the time to read Moderna’s documents page-by-

page. M.MTE R. 17. Dr. Mitchell's opening report is not a book report on Moderna's technical documents; it sets forth his opinions on infringement and the other topics therein. Fed. R. Civ. P. 26(a)(2)(B)(i). For example, his opening report discusses one page of an over 100-page Moderna regulatory document concerning its COVID-19 vaccine, and Moderna offers no reason why Dr. Mitchell was required to examine comprehensively every page where he disclosed only limited opinions about the document. Ex 124 (Mitchell) ¶ 266 (citing MRNA-GEN-01266205).

Under Moderna's standard, it would be impossible for any technical expert (including Moderna's) to spend enough time on reports. For example, Dr. Prud'homme's materials considered for his rebuttal report includes the materials cited in Drs. Mitchell and Schuster's reports and comprise approximately 100,000 pages in total, Ex 123 (Prud'homme Rebuttal) ¶ 15, Ex. A. But Dr. Prud'homme did not review all the materials cited and addressed by Dr. Mitchell: for example, Dr. Mitchell cited and discussed repeatedly a Moderna lab notebook from Dr. Wood regarding its LNP development, yet Dr. Prud'homme was unfamiliar with it. Ex 137 (Prud'homme), 279:11-13, 283:1-5 (testifying that he "d[id]n't believe I reviewed all of [Dr. Wood's] work" and not recalling her lab notebook at deposition); Ex 124 (Mitchell) ¶¶ 221, 231, 234 (discussing Dr. Wood's lab notebook). It would be inconceivable and impossible to read all pages (rather than those relevant to the opinions offered), and neither Dr. Mitchell nor any of Moderna's experts were required to do so. Even Moderna's Mr. Godshalk, who served a report under thirty pages, Ex 135 (Godshalk) at i, testified that he "wouldn't say that I read every page" of an article he cited. Ex 134, 123:10-21. Neither Rule 26 nor any authority supports Moderna's masochistic page-by-page review requirement. Fed. R. Civ. P. 26(a)(2)(B)(i).

Judge Andrews' decision in *First Quality Tissue* is illustrative. There, the plaintiff sought to exclude testimony by alleging that the expert "'reviewed, at most, only isolated lines identified

by [the party's] attorneys and no other portion of transcripts from certain fact witnesses' depositions that he cited in his report," and relied on another expert's "contemporaneously filed report, despite admitting at his deposition that he had not seen [the expert's] report prior to submitting his own report." 2022 WL 958089, at *14. Nonetheless, the court denied "blanket exclusion" of the expert's opinions, because the expert had "substantial involvement" in his report and its technical analysis comprising "the core of his testimony." *Id.* The same is true here, where Dr. Mitchell testified without refutation that he wrote his report in collaboration with counsel and performed the calculations demonstrating infringement. Ex 132, 13:22-24, 190:5-13.

First Quality likewise refutes Moderna's similar criticism that Dr. Mitchell had insufficient time to review Dr. Schuster's report (M.MTE R. 18). There, the expert report included "extensive" reliance on another expert's "contemporaneously filed report" that the expert "***had not seen***" "prior to submitting his own report," but the court nonetheless rejected exclusion. 2022 WL 958089, at *14. Here, the facts weigh even more strongly against exclusion, as Dr. Mitchell undisputedly had the opportunity to review Dr. Schuster's report before signing his own report, M.MTE R. 18, M.Ex. 88, 230:15-21, and Dr. Mitchell's report and testimony demonstrate that he reviewed, understood, and properly relied on Dr. Schuster's work. *E.g.*, Ex 132, 231:15-232:21. For example, Dr. Mitchell had no trouble detailing how Dr. Schuster's fractionation testing demonstrated infringement. *Id.* at 144:8-150:22, 122:16-138:7. Again, Moderna had ample opportunity to refute the veracity of the testing but did not (and could not) point to any error; Moderna instead simply repeats the same arguments the court rejected in *First Quality*.

Moderna's other cited cases are inapposite. Moderna cites several other cases, but all are out-of-circuit cases involving facts that are readily distinguishable from this case. M.MTE R. 20.

In *GEICO v. Right Spinal Clinic, Inc.*, 608 F. Supp. 3d 1184, 1191-92 (M.D. Fla. 2022),

there were “blatant signs of ghostwriting,” where the report bore a “striking resemblance to [another] report,” yet the expert testified he “had not read” the copied report and “did not even know” who its author was. *Id.* at 1190-91. “That the Report borrows so heavily from sources that he has not read indicates that [the expert] did not contribute much to it.” *Id.* at 1191. Likewise, *In re Jackson Ins. Co. Premium Litig.*, 2000 WL 33654070, at *1 (W.D. Mich. Feb. 8, 2000), “[t]he record clearly support[ed]” that the report was written by counsel, including because there were “undeniable substantial similarities between [the] report and the report of another expert” prepared by the same counsel. And in *Bekaert Corp. v. City of Dyersburg*, 256 F.R.D. 573, 579 (W.D. Tenn. 2009), the court similarly found the facts “akin to the situation in which testimony was wholly prepared by counsel with [the expert’s] participation amounting to his signature after reviewing the document.” Here, in contrast, Moderna (1) does not argue that Dr. Mitchell poached material from other reports without attribution, and (2) fails to controvert his un rebutted testimony that he wrote the report in collaboration with counsel, Ex 132, 13:22-24, just like its own experts, *supra* 14, and invested dozens of hours in the report’s preparation, Ex 132, 21:2-5.

Moderna’s last cited case, *Therasense, Inc. v. Becton, Dickinson & Co.*, 2008 WL 2323856, at *3 (N.D. Cal. May 22, 2008), involved an effort to have an expert rely on testing the party itself conducted and “conceal[ed] ... from discovery during all phases of discovery under a claim of privilege.” This case, of course, involves no such effort to “spoon-feed[.]” an expert “client-prepared” facts while shielding them from discovery, *id.* at *1, *3; rather, Moderna had full opportunity to interrogate both Dr. Schuster’s testing and Dr. Mitchell’s infringement opinions and to respond with testing evidence of its own. But rather than contest the merits of Dr. Mitchell’s infringement analysis, Moderna moves to exclude them through this meritless motion. That transparent effort to avoid the un rebutted evidence of infringement should be rejected.

OF COUNSEL:

David I. Berl
Adam D. Harber
Thomas S. Fletcher
Shaun P. Mahaffy
Andrew L. Hoffman
Matthew W. Lachman
Ricardo Leyva
Arthur J. Argall III
Falicia Elenberg
Kathryn Larkin
WILLIAMS & CONNOLLY LLP
680 Maine Avenue S.W.
Washington, DC 20024
(202) 434-5000

Andrei Iancu
Jeffrey B. Wall
Sullivan & Cromwell LLP
1700 New York Avenue, N.W.
Suite 700
Washington, DC 20006
(202) 956-7500

*Attorneys for Plaintiff Genevant
Sciences GmbH*

Daralyn J. Durie
Adam R. Brausa
Eric C. Wiener
Annie A. Lee
Shaelyn K. Dawson
MORRISON & FOERSTER LLP
425 Market Street
San Francisco, CA 94105-2482
(415) 268-6080

Kira A. Davis
MORRISON & FOERSTER LLP

/s/ Nathan R. Hoeschen

John W. Shaw (No. 3362)
Karen E. Keller (No. 4489)
Nathan R. Hoeschen (No. 6232)
SHAW KELLER LLP
I.M. Pei Building
1105 North Market Street, 12th Floor
Wilmington, DE 19801
(302) 298-0700
jshaw@shawkeller.com
kkeller@shawkeller.com
nhoeschen@shawkeller.com

Attorneys for Plaintiffs

707 Wilshire Boulevard
Los Angeles, CA 90017-3543
(213) 892-5200

David N. Tan
MORRISON & FOERSTER LLP
2100 L Street, NW, Suite 900
Washington, DC 20037
(202) 887-1500

*Attorneys for Plaintiff Arbutus
Biopharma Corporation*

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CERTIFICATE OF SERVICE

I hereby certify that on September 23, 2025, this document was served on the persons listed below in the manner indicated:

BY EMAIL:

Brian P. Egan
Travis J. Murray
MORRIS, NICHOLS, ARSHT & TUNNELL LLP
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
began@morrisnichols.com
tmurray@morrisnichols.com

Patricia A. Carson, Ph.D.
Jeanna M. Wacker
Mark C. McLennan
Nancy Kaye Horstman
Shaoyao Yu
Mara L. Greenberg
Leslie M. Schmidt, P.C.
Andrew Lee
Brad Deem
KIRKLAND & ELLIS LLP
601 Lexington Avenue
New York, NY 10022
(212) 446-4800
patricia.carson@kirkland.com
jeanna.wacker@kirkland.com
mark.mclennan@kirkland.com
kaye.horstman@kirkland.com
shaoyao.yu@kirkland.com
mara.greenberg@kirkland.com
leslie.schmidt@kirkland.com
andrew.lee@kirkland.com
brad.deem@kirkland.com

Alina Afinogenova
Noah Frank
KIRKLAND & ELLIS LLP
200 Clarendon Street
Boston, MA 02116
(617) 385-7500
alina.afinogenova@kirkland.com
noah.frank@kirkland.com

James F. Hurst
KIRKLAND & ELLIS LLP
333 West Wolf Point Plaza
Chicago, IL 60654
(312) 862-2000
james.hurst@kirkland.com

Yan-Xin Li
Hannah Suh
Laura Ashley Harris
KIRKLAND & ELLIS LLP
555 California Street, 27th Floor
San Francisco, CA 94104
(415) 439-1400
yanxin.li@kirkland.com
hannah.suh@kirkland.com
lauraashley.harris@kirkland.com

Jason M. Wilcox, P.C.
KIRKLAND & ELLIS LLP
1301 Pennsylvania Avenue, N.W.
Washington, D.C. 20004
(202) 389-5000
jason.wilcox@kirkland.com

/s/ Nathan R. Hoeschen

John W. Shaw (No. 3362)

Karen E. Keller (No. 4489)

Nathan R. Hoeschen (No. 6232)

SHAW KELLER LLP

I.M. Pei Building

1105 North Market Street, 12th Floor

Wilmington, DE 19801

(302) 298-0700

jshaw@shawkeller.com

kkeller@shawkeller.com

nhoeschen@shawkeller.com

Attorneys for Plaintiffs